

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: DONOVAN)	Examiner:
)	
Serial Number: Pending)	
)	Art Unit:
Filed: Herewith)	
)	Confirmation No.
For: ANIMAL PRODUCT FREE MEDIA)	
AND PROCESSES FOR)	
OBTAINING A BOTULINUM TOXIN))	
_____)	Irvine, California

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant provides with regard to the above-identified patent application entitled ANIMAL PRODUCT FREE MEDIA AND PROCESSES FOR OBTAINING A BOTULINUM TOXIN , one copy of documents of which he is aware, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56. A listing of the documents submitted is set forth on the attached 2 page Information Disclosure Citation (Form PTO-1449).


While these documents may be material pursuant to 37 C.F.R. §1.56, the disclosure is not intended to constitute an admission that the documents are prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material

documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.

The Commissioner is hereby authorized to charge any fees required or necessary for the filing, processing or entering of this paper or any of the enclosed papers, and to refund any overpayment, to deposit account 01-0885.

Respectfully submitted,

Date: September 25, 2003


Stephen Donovan
Registration Number 33,433


Please direct all inquiries and correspondence to:

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CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10

I hereby certify that this Information Disclosure Statement and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date September 25, 2003 in an envelope as "Express Mail Post Office to Addressee" Mailing Label number EV295682917US addressed to Mail Stop: Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date September 25, 2003

Susan Bartholomew
Name of person mailing paper

Signature of person signing paper

LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17607 (BOT)	SERIAL NO.:
APPLICANT: STEPHEN DONOVAN	TITLE: ANIMAL PRODUCT FREE MEDIA AND PROCESSES FOR OBTAINING A BOTULINUM TOXIN
FILING DATE: herewith	GROUP:

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	6,558,926 B1	5/6/03	Demain, et al.			
	AB	2003/0118598A1		Hunt, et al.			11/5/02
	AC						
	AD						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/n)
	BA						
	BB						
	BC						

OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

	CA	Bonventre, P.F., et al., Physiology of toxin production by clostridium botulinum types A and B, <i>College of Medicine, Vol. 7, pgs. 372-374</i>
	CB	Chen, F., et al., Biophysical characterization of the stability of the 150-kilodalton botulinum toxin, the nontoxic component and the 900-kilodalton botulinum toxin complex species, <i>Infect Immun</i> 1998 Jun;66(6):2420-2425
	CC	Holdeman, L., et al., A study of the nutritional requirements and toxin production of clostridium botulinum type F, <i>Canadian Journal of Microbiology</i> , Vol 11, (1965), pp. 1009-1019
	CD	Johnson, E., et al., Clostridium botulinum and its neurotoxins: a metabolic and cellular perspective, <i>Toxicon</i> 39 (2001) 1703-1722
	CE	Karasawa, T., et al., A defined growth medium for clostridium difficile, <i>Microbiology</i> (1995),141, 371-375
	CF	Kohl, A., et al., Comparison of the effect of botulinum toxin A (BOTOX®) with the highly-purified neurotoxin (NT201) n the extensor digitorum brevis muscle test, <i>MOV DISORD</i> , 2000;15(Suppl 3):165
	CG	Lewis, K.H., et al., Practical media and control measures for highly toxic cultures of clostridium botulinum type A, <i>Production of Botulinum Toxin</i> , pgs. 213-230.
	CH	Li, Y., et al., Expression and characterization of the heavy chain of tetanus toxin: reconstitution of the fully-recombinant dichain protein in active form, <i>J Biochem (Tokyo)</i> 1999 Jun;125(6):1200-1208

EXAMINER _____ **DATE CONSIDERED** _____

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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APPLICANT: STEPHEN DONOVAN	TITLE: ANIMAL PRODUCT FREE MEDIA AND PROCESSES FOR OBTAINING A BOTULINUM TOXIN
FILING DATE: herewith	GROUP:

	CI	Naumann, M., et al., Botulinum toxin type A in the treatment of focal, axillary and palmar hyperhidrosis and other hyperhidrotic conditions, <i>Euro. J. Neurology</i> 1999:6(Suppl 4):S111-S115
	CJ	Porfirio, Z., et al., Specific peptides of casein pancreatic digestion enhance the production of tetanus toxin, <i>J. of Applied Microbiology</i> , 1997 83:678-684
	CK	Ragona, Rosario Marchese, et al., Management of Parotid Sialoceles with botulinum toxin, <i>The Laryngoscope</i> , 109:August 1999:pp. 1344-1346
	CL	Siegel, L.S., Fermentation kinetics of botulinum toxin production (types A, B and E), <i>Biomedical aspects of botulism</i> , New York: Academic Press 1981:pp 121-8
	CM	Schantz, E.J., et al., Preparation and characterization of botulinum toxin type A for human treatment, Jankovic J, ed.; <i>Neurological Disease and Therapy. Therapy with Botulinum Toxin</i> , 1994;25:pp. 41-49
	CN	Schantz, E.J., et al., Properties and use of botulinum toxin and other microbial neurotoxins in medicine, <i>Microbiological Reviews</i> , Mar 1992, p. 80-99
	CO	Schiefer-Ullrich, H., et al., Comparative studies on physiology and taxonomy of obligatory purinolytic clostridia, <i>Arch Microbiol</i> , 1984, 138:345-353
	CP	Whitmer, M.E., et al., Development of improved defined media for clostridium botulinum serotypes A, B and E, <i>Applied and Environmental Microbiology</i> , Mar 1988, Vol. 54, No. 3, p. 753-759
	CQ	

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